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APR 16 2002

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In re Application of	:
Michael W. Dahm et al.	:
Serial No.:09/601,645	:PETITION DECISION
Filed: August 4, 2000	:
Attorney Docket No.: 24741-1509US	:

This is in response to applicant's petition, filed December 26, 2001 under 37 CFR 1.144, requesting removal of the restriction requirement set forth by the examiner. The delay in responding to this petition is regretted.

BACKGROUND

A review of the file history shows that this application was filed under 35 U.S.C. 371 as the National Stage of PCT/EP99/00716, filed February 3, 1999, which claims priority to German application 198 04 372.4, filed February 4, 1998. The application, as filed, contains claims 1-51 and 52-68 presented in a preliminary amendment. In a first Office action mailed May 1, 2001, the examiner set forth a restriction / lack of unity requirement under 35 U.S.C. 121 and 372 dividing the claims into 2 groups, as follows:

> Group I, claims 1-38 and 52-67, drawn to a nucleic acid amplification method.
> Group II, claims 39-51 and 68, drawn to an oligonucleotide and a kit containing said oligonucleotide.

The examiner presented reasons for the requirement, indicating that the cDNA sequence of human telomerase was known in the art and that methods of quantifying tumor cells in body fluid by measuring specific mRNAs in cells were also known in the art. Applicant replied by electing, with traverse, Group I, claims 1-38 and 52-67. Applicant argued that the inventions of both groups are not taught or suggested by the prior art, and therefore they are linked by a special technical feature.

In the next Office action, mailed July 3, 2001, the examiner modified the restriction requirement by dividing the claims into 3 groups, as follows:

> Group I, claims 1-19, 35-38 and 52-61, drawn to a nucleic acid amplification method.

Group II, claims 20-34 and 62-67, drawn to a method and apparatus for concentrating tumor cells.
Group III, claims 39-51 and 68, drawn to an oligonucleotide and a kit containing said oligonucleotide.

The examiner presented reasons for the requirement, indicating that the cDNA sequence of human telomerase was known in the art and that methods of quantifying tumor cells in body fluid by measuring specific mRNAs in cells were also known in the art, citing an additional reference. The examiner did not respond to Applicant's arguments.

Applicant replied by electing, with traverse, Group II, claims 20-34 and 62-67. Applicant again argued that the inventions of all groups are not taught or suggested by the prior art, and therefore they are linked by a special technical feature. Applicant further argued that the restriction requirement could result in applicant being granted two patents on essentially the same method (Groups I and II) without a double patenting rejection being made.

In the next Office action, mailed October 24, 2001, the examiner again modified the restriction requirement, stating that claim 67 should have been included in Group I because it depends on claim 1. The examiner made the restriction requirement final, responding to Applicant's arguments as follows. The examiner stated that none of the particulars of amplifying and quantifying RNA are found in Group II, while none of the particulars of concentrating tumor cells are found in Group I. Therefore, the examiner reasoned, the special technical feature is the human telomerase sequence, which was known in the art.

DISCUSSION

In the petition, Applicant disputes the examiner's assertion that the telomerase sequence is the general inventive feature of groups I and II. Applicant does not suggest an alternative special technical feature, but points out that the claims of Groups I and II are all drawn to a methods for quantitation of tumor cells and that all the claims of Group II are dependent on claims of Group I. Applicant also argues that the primers of Group III are specified in some dependent claims of group I.

Annex B of the PCT Administrative Instructions gives guidance on Unity of Invention as follows:

> (c) Unity of invention has to be considered in the first place only in relation to the independent claims in an international application and not the dependent claims. By "dependent" claim is meant a claim which contains all the features of another claim and is in the same category of claim as that other claim (the expression "category of claim" referring to the classification of claims according to the subject matter of the invention claimed, for example, product, process, use or apparatus or means, etc.).

There are 4 independent claims pending in the instant application: claims 1 and 39-41. Claim 1 is drawn to a method for quantification of tumor cells in a body fluid, comprising specifically amplifying mRNA coding for the catalytic subunit of telomerase. Claim 41 is drawn to a kit comprising an oligonucleotide primer pair for amplifying the catalytic subunit of telomerase. Claims 39 and 40 are drawn to oligonucleotide primers having specific sequences. Claim 1 does not require the specific sequence of claims 39 and 40. Neither claim 1 nor claim 41 recite a

specific sequence, and the specification states that any sequence section of the cDNA encoding the catalytic subunit of telomerase may be used in the invention (p. 7, lines 35-38). Therefore it is concluded that there is no common structure uniting the compositions of claims 39-41 with the method of claim 1, and restriction of claims 39-51 and 68 (Group III) from the other claims is proper.

Claim 20, which depends on claim 1, was rejected by the examiner under 35 U.S.C. 103. Therefore claim 1 is not free of the prior art. Annex B part (c)(ii) states, in part:

> If, however, an independent claim does not avoid the prior art, then the question whether there is still an inventive link between all the claims dependent on that claim needs to be carefully considered.

In this case, all the claims of group II ultimately depend on claim 1. The claims of Group II may contain a technical feature not found in claim 1, but the technical feature of claim 1 is included in each of the Group II claims. Therefore there is still an inventive link between claims 1-38 and 52-67 and further restriction of these claims is deemed improper.

DECISION

Applicant's petition with respect to withdrawal of the restriction / lack of unity requirement is **GRANTED-IN-PART** for the reasons set forth above.

The application will be forwarded to the examiner for consideration of claims 1-38 and 52-67, in light of Applicant's response filed February 25, 2002, following mailing of this decision.

Any request for reconsideration or review of this decision must be made by a renewed petition and must be filed within TWO MONTHS of the mailing date of this decision in order to be considered timely.

Should there be any questions with regard to this letter please contact Bruce Campell by letter addressed to the Director, Technology Center 1600, Washington, DC 20231, or by telephone at (703) 308-4205 or by facsimile transmission at (703) 746-5006.

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